EXHIBIT 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-436

NDA APPROVAL

Medivir AB
c/o B&H Consulting Services, Inc.
Attn: Elizabeth Dupras
55 North Gaston Avenue
Somerville, NJ 08876

Dear Ms. Dupras:

Please refer to your new drug application (NDA) dated September 30, 2008, received October 1, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Acyclovir and Hydrocortisone Cream, 5%/1%, Topical.

We acknowledge receipt of your submissions dated:

October 28, 2008	April 16, 2009	May 8, 2009
October 30, 2008	April 17, 2009	June 2, 2009
November 19, 2008	April 20, 2009	June 29, 2009
December 5, 2008	April 23, 2009	July 20, 2009
December 23, 2008	April 30, 2009	July 30, 2009

This new drug application provides for the use of Acyclovir and Hydrocortisone Cream for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and adolescents (12 years of age and older).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-436.**"

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-436.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROPRIETARY NAME

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages less than 6 years of age because necessary studies are impossible or highly impracticable and the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group. This is because of the pathophysiology and epidemiology of the disease. Herpes labialis in children less than 6 years of age is generally a primary infection, and not a recurrence.

We are deferring submission of your pediatric study for ages greater than 6 years to less than 12 years for this application because this product is ready for approval for use in adults and adolescents (12 years of age and older).

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

1500-1. Deferred pediatric study under PREA for the treatment of recurrent herpes labialis in pediatric patients ages greater than 6 years to less than 12 years.

Final Report Submission: May 1, 2013

Submit final study reports to this NDA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated "**Required Pediatric Assessment**".

We note that you have fulfilled the pediatric study requirement for ages greater than 12 years for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call David Araojo, Pharm.D., Regulatory Project Manager, at (301) 796-0669.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure (Package Insert, Patient Package Insert, Carton and Container Labels)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Acyclovir and Hydrocortisone Cream safely and effectively. See full prescribing information for Acyclovir and Hydrocortisone Cream.

Acyclovir and Hydrocortisone Cream for topical use

Initial U.S. Approval: 2009

----------INDICATIONS AND USAGE----------

Acyclovir and Hydrocortisone Cream, a combination of acyclovir and hydrocortisone, is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and adolescents (12 years of age and older) (*1*).

----------DOSAGE AND ADMINISTRATION----------

Topically apply Acyclovir and Hydrocortisone Cream 5 times per day for 5 days. Therapy should be initiated as early as possible after the first signs and symptoms (i.e., during the prodrome or when lesions appear) (*2*).

----------DOSAGE FORMS AND STRENGTHS----------

Topical cream containing 5% acyclovir and 1% hydrocortisone (*3*).

----------CONTRAINDICATIONS----------

None.

----------WARNINGS AND PRECAUTIONS----------

- Only for topical use of recurrent herpes labialis on the lips and around the mouth (*5*).

----------ADVERSE REACTIONS----------

The following most common adverse reactions (< 1%) were local skin reactions (*6.2*):

- Drying or flaking of the skin; burning or tingling, erythema; pigmentation changes.

To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

No drug interaction studies have been performed with Acyclovir and Hydrocortisone Cream.

----------USE IN SPECIFIC POPULATIONS----------

- Immunocompromised Patients: Benefit has not been adequately assessed (8.6).

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 07/2009

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Acyclovir and Hydrocortisone Cream is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and adolescents (12 years of age and older).

2 DOSAGE AND ADMINISTRATION

Topically apply Acyclovir and Hydrocortisone Cream 5 times per day for 5 days. Therapy should be initiated as early as possible after the first signs and symptoms (i.e., during the prodrome or when lesions appear).

For each dose, topically apply a quantity of Acyclovir and Hydrocortisone Cream sufficient to cover the affected area, including the outer margin. Avoid unnecessary rubbing of the affected area to avoid aggravating or transferring the infection. For adolescents 12 years of age and older, the dosage is the same as in adults.

3 DOSAGE FORMS AND STRENGTHS

Each gram of Acyclovir and Hydrocortisone Cream contains 5% (w/w) acyclovir and 1% (w/w) hydrocortisone in an aqueous cream base.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 General

Acyclovir and Hydrocortisone Cream is intended for cutaneous use only for herpes labialis of the lips and around the mouth. Acyclovir and Hydrocortisone Cream should not be used in the eye, inside the mouth or nose, or on the genitals.

There are other orofacial lesions, including bacterial and fungal infections, which may be difficult to distinguish from a cold sore. Patients should be encouraged to seek medical advice when a cold sore fails to heal within 2 weeks.

Acyclovir and Hydrocortisone Cream has a potential for irritation and contact sensitization [*see Adverse Reactions (6)*].

6 ADVERSE REACTIONS

6.1 Overall Adverse Reaction Profile

The safety data derived from Acyclovir and Hydrocortisone Cream clinical studies reflects exposure to Acyclovir and Hydrocortisone Cream in 1002 subjects with recurrent herpes labialis treated 5 times daily for 5 days. The majority of the adverse reactions were local skin reactions and occurred in the area of the application site.

6.2 Adverse Reactions in Clinical Studies

Because clinical studies are conducted under widely varying conditions, the adverse reaction rates observed cannot be directly compared to rates in other clinical studies and may not reflect the rates observed in clinical practice.

The majority of the adverse reactions were local and occurred in the area of the application site.

Skin and Subcutaneous Tissue Disorders

The following most common adverse reactions (< 1%) were local skin reactions, and occurred in the area of the application site:

-Drying or flaking of the skin; burning or tingling following application; erythema; pigmentation changes; application site reaction including signs and symptoms of inflammation.

Contact dermatitis following application has been observed when applied under occlusion in dermal safety studies. Where contact sensitivity tests have been conducted, the reactive substances were hydrocortisone or a component of the cream base.

A study enrolling 225 healthy adults was conducted to evaluate the contact sensitization potential of Acyclovir and Hydrocortisone Cream using repeat insult patch testing methodology. Of 205 evaluable subjects, one confirmed case (0.5%) of sensitization to hydrocortisone and 2 additional cases (1.0%) of possible sensitization to the Acyclovir and Hydrocortisone Cream base were identified. Additionally, one subject developed a contact allergy in the photosafety study to propylene glycol, one of the inactive ingredients of the cream base.

Dermal tolerance was assessed in a 21-day cumulative irritation study in 36 healthy subjects. Acyclovir and Hydrocortisone Cream, its cream base and Zovirax® (acyclovir) Cream 5% all showed a high and cumulative irritation potential under occlusive and semi-occlusive conditions.

Photoallergic potential and phototoxicity were assessed in two studies in 50 and 30 healthy volunteers, respectively. No photoallergic or phototoxicity potential was identified for Acyclovir and Hydrocortisone Cream.

7 DRUG INTERACTIONS

No drug interaction studies have been performed with Acyclovir and Hydrocortisone Cream.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Category B

Teratogenic Effects:

Acyclovir was not teratogenic in the mouse, rabbit or rat at exposures greatly in excess of human exposure. There are no adequate and well-controlled studies of systemic acyclovir in pregnant women. A prospective epidemiologic registry of acyclovir use during pregnancy between 1984 and 1999 followed 749 pregnancies in women exposed to systemic acyclovir during the first trimester of pregnancy resulting in 756 outcomes. The occurrence rate of birth defects approximated that found in the general population. However, the size of the registry was insufficient to evaluate the risk for less common defects or to permit reliable or definitive conclusions regarding the safety of acyclovir in pregnant women and their developing fetuses.

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Animal reproduction studies have not been conducted with Acyclovir and Hydrocortisone Cream. No studies have been performed in pregnant women. Systemic exposure of acyclovir and hydrocortisone following topical administration of Acyclovir and Hydrocortisone Cream is minimal.

8.3 Nursing Mothers

It is not known whether topically applied acyclovir or hydrocortisone is excreted in breast milk. Systemic exposure following topical administration of either drug is expected to be below detection limits. Because many drugs are excreted in human milk, caution should be exercised when Acyclovir and Hydrocortisone Cream is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric subjects less than 12 years of age have not been established.

8.5 Geriatric Use

In clinical studies, there were insufficient subjects above 65 years of age to reach a firm conclusion regarding safety and efficacy of Acyclovir and Hydrocortisone Cream in this group, although the available results were similar to lower age subjects.

8.6 Immunocompromised Subjects

Even though the safety of Acyclovir and Hydrocortisone Cream has been studied in immunocompromised subjects, data are insufficient to support use in this population. Immunocompromised subjects should be encouraged to consult a physician concerning the treatment of any infection.

Benefit has not been adequately assessed in immunocompromised patients. A randomized, double-blind study was conducted in 107 immunocompromised subjects with stable HIV infection and recurrent herpes labialis. Subjects had on average 3.7 episodes of herpes labialis in the previous 12 months. The median age was 30 years (range 19 to 64 years), 46% were female, and all Caucasian. Median CD4+ T-cell count at screening was 344/mm^3 (range 100-500/mm^3). Subjects were treated with Acyclovir and Hydrocortisone Cream or 5% acyclovir in Acyclovir and Hydrocortisone Cream vehicle. The primary objective was to exclude a doubling of the healing time in either treatment arm. The mean healing time for cold sores was similar between the two treatment groups: 6.6 days for Acyclovir and Hydrocortisone Cream and 6.9 days for 5% acyclovir in Acyclovir and Hydrocortisone Cream vehicle.

10 OVERDOSAGE

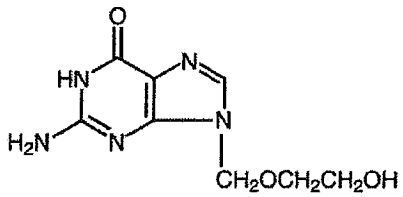
Overdosage by topical application of Acyclovir and Hydrocortisone Cream is unlikely because of minimal systemic exposure [*see Clinical Pharmacology- Pharmacokinetics (12.3)*].

11 DESCRIPTION

Acyclovir and Hydrocortisone Cream contains acyclovir, a synthetic nucleoside analogue active against herpes viruses, and hydrocortisone, an anti-inflammatory corticosteroid, combined in a cream for topical administration. Each gram of Acyclovir and Hydrocortisone Cream contains 5% (w/w) of acyclovir, 1% (w/w) of hydrocortisone and the following inactive ingredients: cetostearyl alcohol, mineral oil, Poloxamer 188, propylene glycol, isopropyl myristate, sodium lauryl sulfate, white petrolatum, citric acid, sodium hydroxide and water. Sodium hydroxide or hydrochloric acid may be added to adjust the pH to approximately pH 5.

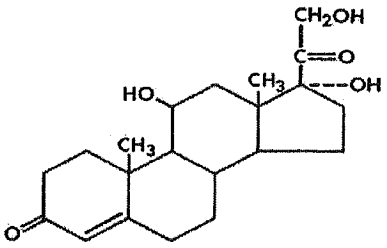
Acyclovir, 2-amino-1,9-dihydro-9-[(2-hydroxyethoxy)methyl]-6H-purin- 6-one, is a synthetic nucleoside analogue active against herpes viruses. The maximum solubility of acyclovir in water at 37°C is 2.5 mg/mL. The pKa's of acyclovir are 2.27 and 9.25. Its empirical formula is $C_8H_{11}N_5O_3$. The structural formula is provided in Figure 1:

Figure 1: Structural Formula of Acyclovir



Hydrocortisone, pregn-4-ene-3, 20-dione, 11, 17, 21-trihydroxy-(11(beta))-, is an anti-inflammatory corticosteroid. Its empirical formula is $C_{21}H_{30}O_5$. The structural formula is provided in Figure 2:

Figure 2: Structural Formula of Hydrocortisone



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Acyclovir is an antiviral drug and hydrocortisone an anti-inflammatory drug. [see *Clinical Pharmacology - Microbiology (12.4)*].

12.3 Pharmacokinetics

The plasma concentrations of acyclovir and hydrocortisone were not measured following topical administration of Acyclovir and Hydrocortisone Cream on cold sores.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin and can have systemic side effects depending on both the potency of the corticosteroid and the surface area of application. Inflammation and/or other disease processes in the skin that disrupt the skin barrier can increase percutaneous absorption.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. They are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

12.4 Microbiology

Mechanism of Action

Acyclovir is a synthetic purine nucleoside analogue with inhibitory activity against herpes simplex viruses type 1 (HSV-1) and type 2 (HSV-2) in cell culture and *in vivo*.

The inhibitory activity of acyclovir is highly selective due to its affinity for the enzyme thymidine kinase (TK) encoded by HSV. This viral enzyme converts acyclovir into acyclovir monophosphate, a nucleotide analogue. The monophosphate is further converted into diphosphate by cellular guanylate kinase and into triphosphate by a number of cellular enzymes. In cell culture, acyclovir triphosphate stops replication of herpes viral DNA. This inhibition is accomplished in 3 ways: 1) competitive inhibition of viral DNA polymerase, 2) incorporation into and termination of the growing viral DNA chain, and 3) inactivation of the viral DNA polymerase.

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It is used topically for its anti-inflammatory effects which suppress the clinical manifestations of the disease in a wide range of disorders where inflammation is a prominent feature.

Antiviral Activity

The quantitative relationship between the cell culture susceptibility of herpes viruses to antivirals and the clinical response to therapy has not been established in humans, and virus sensitivity testing has not been standardized. Sensitivity testing results, expressed as the concentration of drug required to inhibit by 50% the growth of virus in cell culture (EC_{50}), vary greatly depending upon a number of factors. Using plaque-reduction assays on Vero cells, the median EC_{50} value of acyclovir against clinical herpes virus isolates (subjects receiving placebo) was 1.3 μM (range: < 0.56 to 3.3 μM).

Resistance

Resistance of HSV to acyclovir can result from qualitative and quantitative changes in the viral TK and/or DNA polymerase. Clinical isolates of HSV with reduced susceptibility to acyclovir have been recovered from immunocompromised subjects, especially with advanced HIV infection. While most of the acyclovir-resistant mutants isolated from immunocompromised subjects thus far have been found to be TK-deficient mutants, other mutants involving the viral TK gene (TK partial and TK altered) and DNA polymerase have been isolated. TK-negative mutants may cause severe disease in infants and immunocompromised adults.

The possibility of viral resistance to acyclovir should be considered in patients who show poor clinical response during therapy.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Systemic exposure following topical administration of acyclovir is minimal. Results from previous studies of carcinogenesis, mutagenesis and fertility for acyclovir and hydrocortisone are not included in the full prescribing information for Acyclovir and Hydrocortisone Cream due to the minimal exposures that result from dermal application. Information on these studies following systemic exposure is available in the full prescribing information for acyclovir and hydrocortisone products approved for oral or parenteral administration. Dermal carcinogenicity studies have not been conducted.

14 CLINICAL STUDIES

Adults: A double-blind, randomized clinical study involving 1443 subjects with recurrent labial herpes treated with Acyclovir and Hydrocortisone Cream, 5% acyclovir in Acyclovir and Hydrocortisone Cream vehicle or vehicle alone. Subjects had, on average, 5.6 episodes of herpes labialis in the previous 12 months. The median age was 44 years (range 18 to 80 years), 72% were female, and 91% were Caucasian. Subjects were instructed to initiate treatment within 1 hour of noticing signs or symptoms and continue treatment for 5 days, with application of study medication 5 times per day. Ulcerative cold sores occurred in 58% of the subjects treated with Acyclovir and Hydrocortisone Cream compared to 74% in subjects treated with vehicle and 65% in subjects treated with 5% acyclovir in Acyclovir and Hydrocortisone Cream vehicle. The mean time to skin normalization was approximately 1.6 days shorter in the subjects treated with Acyclovir and Hydrocortisone Cream compared to vehicle. Clinical signs in terms of size of the cold sore and symptoms such as tenderness were reduced with Acyclovir and Hydrocortisone Cream as compared to vehicle.
Pediatric Subjects: An open label safety study in adolescents with recurrent herpes labialis was conducted in 134 subjects. Subjects had, on average, 4.0 episodes of herpes labialis in the previous 12 months. The median age was 14 years (range 12 to 17 years); 50% were female and all were Caucasian. Therapy was applied using the same dosing regimen as in adults and subjects were monitored for adverse events and selected efficacy parameters. The safety and efficacy profile appeared similar to that observed in adults.

16 HOW SUPPLIED/STORAGE AND HANDLING

Acyclovir and Hydrocortisone Cream is supplied in plastic-laminated aluminum tubes containing 2 gm or 5 gm of Acyclovir and Hydrocortisone Cream. Each gram of Acyclovir and Hydrocortisone Cream contains 5% (w/w) acyclovir and 1% (w/w) hydrocortisone in an aqueous cream base.
NDC XXXXX-XXX-XXX: 2-gm tubes
NDC XXXXX-XXX-XXX: 5-gm tubes
Store at Controlled Room Temperature [up to 25°C (77°F); excursions permitted to 30°C (86°F). Do not freeze.]

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (17.1).

17.1 FDA-Approved Patient Labeling

PATIENT INFORMATION
Acyclovir and Hydrocortisone Cream

Acyclovir and Hydrocortisone Cream is for cold sores on lips and around the mouth only. Acyclovir and Hydrocortisone Cream should not be used in eyes, mouth, nose or on genitals.

Read this Patient Information that comes with Acyclovir and Hydrocortisone Cream before you start using it and each time you get a refill. There may be new information. This patient leaflet does not take the place of talking with your doctor about your medical condition or treatment.

What is Acyclovir and Hydrocortisone Cream?
Acyclovir and Hydrocortisone Cream is a prescription medicine used in people ages 12 and older to lessen the healing time of cold sores (herpes labialis) and lessen the chance of a cold sore becoming worse (ulcerating). Acyclovir and Hydrocortisone Cream is not a cure for cold sores.
It is not known if Acyclovir and Hydrocortisone Cream is safe or works in children younger than 12 years old.

What should I tell my doctor before using Acyclovir and Hydrocortisone Cream?
Before you use Acyclovir and Hydrocortisone Cream, tell your doctor if you:
- have a weak immune system (become sick very easily). It is not known if Acyclovir and Hydrocortisone Cream will harm you.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if Acyclovir and Hydrocortisone Cream will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if Acyclovir and Hydrocortisone Cream is passed in your milk to your baby.

How should I use Acyclovir and Hydrocortisone Cream?
- Use Acyclovir and Hydrocortisone Cream exactly as directed by your doctor.
- Use Acyclovir and Hydrocortisone Cream early, at the first sign of a cold sore.
- Wash your hands before and after using Acyclovir and Hydrocortisone Cream.
- Clean and dry the skin before applying Acyclovir and Hydrocortisone Cream.
- Spread a thin layer of Acyclovir and Hydrocortisone Cream on the affected area.
- Do not rub the cold sore because it may spread to other areas around your mouth, or make your cold sore worse.
- Do not cover the cold sore or area around the cold sore with a bandage.
- Do not use other skin products (such as make-up, sun screen or lip balm) or other skin medicine on the cold sore or area around the cold sore.
- Do not bathe, shower or swim until 30 minutes after applying Acyclovir and Hydrocortisone Cream.
- Talk to your doctor if your cold sore is not better in 2 weeks.

What are the possible side effects of Acyclovir and Hydrocortisone Cream?
The most common side effects of Acyclovir and Hydrocortisone Cream are:
- drying or flaking of the skin
- tingling or burning after you apply Acyclovir and Hydrocortisone Cream
- redness of the skin
- changes in your skin color where the cream is applied (pigmentation changes)
- swelling where Acyclovir and Hydrocortisone Cream was applied
- bitter taste after you apply Acyclovir and Hydrocortisone Cream.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Acyclovir and Hydrocortisone Cream. For more information, ask your doctor or pharmacist.
Call you doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

How should I store Acyclovir and Hydrocortisone Cream?
- Store up to 77°F (25°C); excursions permitted to 86°F (30°C).
- Do not freeze Acyclovir and Hydrocortisone Cream.
- Keep the Acyclovir and Hydrocortisone Cream tube closed tightly.

Keep Acyclovir and Hydrocortisone Cream and all medicines out of the reach of children.

General Information about Acyclovir and Hydrocortisone Cream
Medicines are sometimes prescribed for conditions that are not mentioned in patient leaflets. Do not use Acyclovir and Hydrocortisone Cream for a condition for which it was not prescribed. Do not give Acyclovir and Hydrocortisone Cream to other people, even if they have the same symptoms you have. It may harm them.

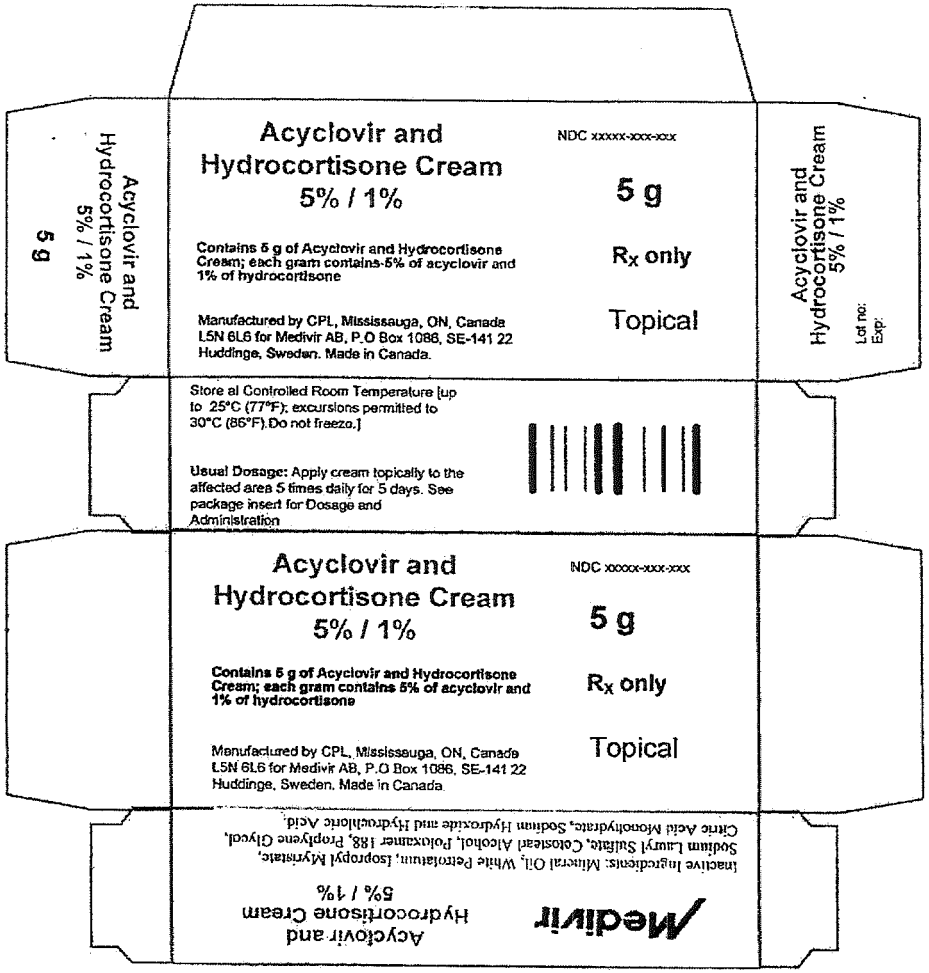
This patient leaflet summarizes the most important information about Acyclovir and Hydrocortisone Cream. If you would like to know more information about Acyclovir and Hydrocortisone Cream, talk with your doctor. You can ask your doctor or pharmacist for additional information about Acyclovir and Hydrocortisone Cream that was written for healthcare professionals.

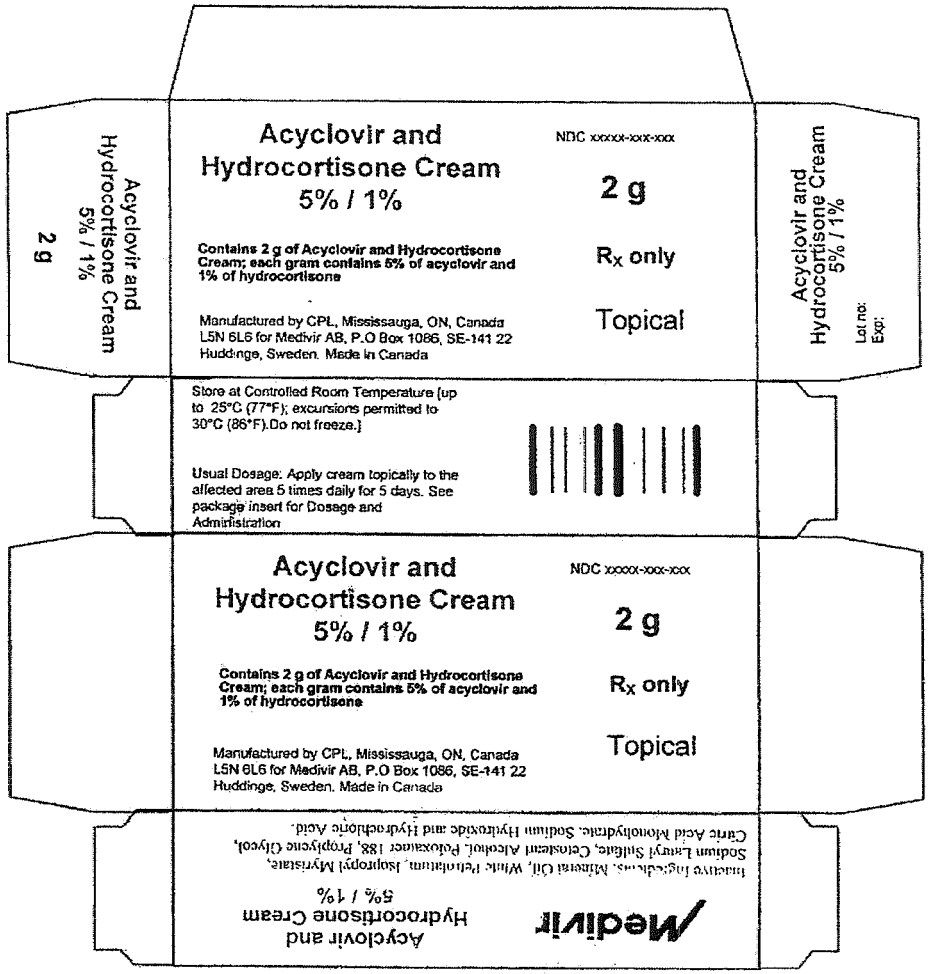
What are the ingredients of Acyclovir and Hydrocortisone Cream?
Active Ingredients: acyclovir and hydrocortisone
Inactive ingredients: cetostearyl alcohol, mineral oil, Poloxamer 188, propylene glycol, isopropyl myristate, sodium lauryl sulfate, white petrolatum, citric acid, sodium hydroxide and water.

Rx Only **Revised: 07/2009**

Manufactured for:
Medivir AB
PO Box 1086
SE-141 22 Huddinge
SWEDEN

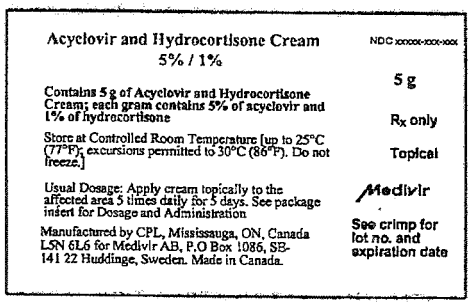
Manufactured by:
Contract Pharmaceuticals Limited
7600 Danbro Crescent
Mississauga, Ontario
CANADA L5N 6L6


Acyclovir and
Hydrocortisone Cream
5% / 1%
5 g
Acyclovir and
Hydrocortisone Cream
5% / 1%
NDC xxxxx-xxx-xxx
5 g
Rx only
Topical
Contains 5 g of Acyclovir and Hydrocortisone Cream; each gram contains 5% of acyclovir and 1% of hydrocortisone
Manufactured by CPL, Mississauga, ON, Canada L5N 6L6 for Medivir AB, P.O Box 1086, SE-141 22 Huddinge, Sweden. Made in Canada.
Acyclovir and
Hydrocortisone Cream
5% / 1%
Lot no:
Exp:
Store at Controlled Room Temperature [up to 25°C (77°F); excursions permitted to 30°C (86°F).Do not freeze.]
Usual Dosage: Apply cream topically to the affected area 5 times daily for 5 days. See package insert for Dosage and Administration
Acyclovir and
Hydrocortisone Cream
5% / 1%
NDC xxxxx-xxx-xxx
5 g
Rx only
Topical
Contains 5 g of Acyclovir and Hydrocortisone Cream; each gram contains 5% of acyclovir and 1% of hydrocortisone
Manufactured by CPL, Mississauga, ON, Canada L5N 6L6 for Medivir AB, P.O Box 1086, SE-141 22 Huddinge, Sweden. Made in Canada.
Acyclovir and
Hydrocortisone Cream
5% / 1%
Medivir
Inactive Ingredients: Mineral Oil, White Petrolatum, Isopropyl Myristate, Sodium Lauryl Sulfate, Cetostearl Alcohol, Poloxamer 188, Propylene Glycol, Citric Acid Monohydrate, Sodium Hydroxide and Hydrochloric Acid.

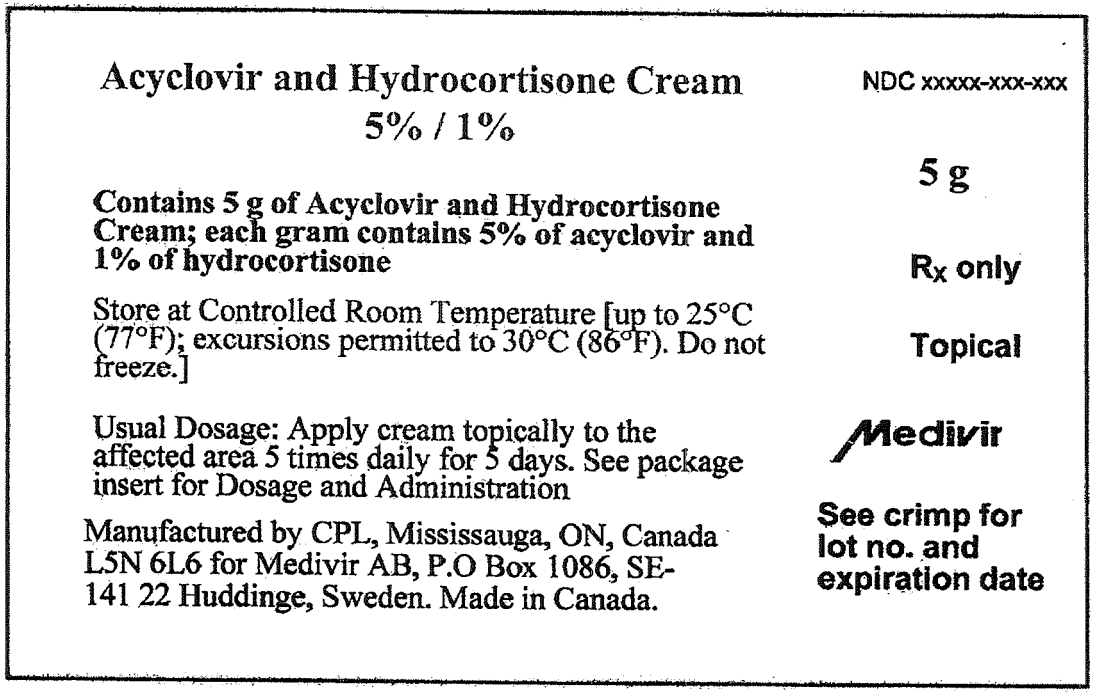

Acyclovir and
Hydrocortisone Cream
5% / 1%
2 g
Acyclovir and
Hydrocortisone Cream
5% / 1%
NDC xxxxx-xxx-xx
2 g
Rx only
Topical
Contains 2 g of Acyclovir and Hydrocortisone Cream; each gram contains 5% of acyclovir and 1% of hydrocortisone
Manufactured by CPL, Mississauga, ON, Canada
L5N 6L6 for Medivir AB, P.O Box 1086, SE-141 22
Huddinge, Sweden. Made in Canada
Store at Controlled Room Temperature (up to 25°C (77°F); excursions permitted to 30°C (86°F).Do not freeze.]
Usual Dosage: Apply cream topically to the affected area 5 times daily for 5 days. See package insert for Dosage and Administration
Acyclovir and
Hydrocortisone Cream
5% / 1%
Lot no:
Exp:
Acyclovir and
Hydrocortisone Cream
5% / 1%
NDC xxxxx-xxx-xx
2 g
Rx only
Topical
Contains 2 g of Acyclovir and Hydrocortisone Cream; each gram contains 5% of acyclovir and 1% of hydrocortisone
Manufactured by CPL, Mississauga, ON, Canada
L5N 6L6 for Medivir AB, P.O Box 1086, SE-141 22
Huddinge, Sweden. Made in Canada
Medivir
Acyclovir and
Hydrocortisone Cream
5% / 1%
Inactive Ingredients: Mineral Oil, White Petrolatum, Isopropyl Myristate, Sodium Lauryl Sulfate, Cetostearl Alcohol, Poloxamer 188, Propylene Glycol, Citric Acid Monohydrate, Sodium Hydroxide and Hydrochloric Acid.

Cream, 5-g Tube

(Actual Size)

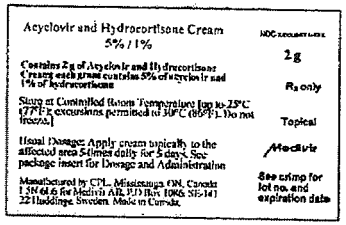


(Enlarged View)



Cream, 2-g Tube

(Actual Size)



(Enlarged View)

Acyclovir and Hydrocortisone Cream 5% / 1%

NDC xxxxx-xxx-xxx

2 g

Contains 2 g of Acyclovir and Hydrocortisone Cream; each gram contains 5% of acyclovir and 1% of hydrocortisone

R_x only

Store at Controlled Room Temperature [up to 25°C (77°F); excursions permitted to 30°C (86°F). Do not freeze.]

Topical

Usual Dosage: Apply cream topically to the affected area 5 times daily for 5 days. See package insert for Dosage and Administration

Medivir

Manufactured by CPL, Mississauga, ON, Canada L5N 6L6 for Medivir AB, P.O Box 1086, SE-141 22 Huddinge, Sweden. Made in Canada.

See crimp for lot no. and expiration date

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/s/

JEFFREY S MURRAY
07/31/2009